DETAILED ACTION

Claims 1-8 are pending in the instant application.

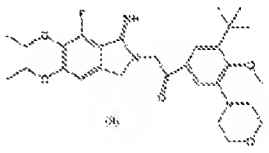
Information Disclosure Statement

Applicants' Information Disclosure Statements, filed on 08/28/2006, and 01/16/2008, have been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

Priority

This application is a 371 of PCT/JP05/03742 filed on 03/04/2005, which claims the benefit of foreign priority of Japan Patent Application 2004-061472, filed on 03/04/2004.

Response to Restriction

Applicants' election with traverse of Groups I/II (claims 1-5) drawn to a composition with elected species of the compound  in the reply filed on 03/11/2008 is acknowledged. The Examiner has agreed to examine Groups I and II together, and the restriction requirement between the two groups hereby withdrawn.

Status of the Claims

Claims 6-8 are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR 1.142(b) due to the restriction requirement. The initial search was conducted and the elected species of the composition is obvious to a prior art teaching. For this reason, the whole invention is treated as lack of unity of invention, and the scope of invention is further reduced from claims 1-5 into only the elected species and its obvious related species in claim 1-5, see MPEP§803.02 under Markush Claims.

Therefore, claims 1-5 (in part) will be examined on the merits.

Specification

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from. An appropriate amendment is required.

Claim Objections

Claim 1 is objected to because the parentheses " (wherein R^1 and R^2, and C_{1-4} alkyl group.) " render the claim ambiguous. This objection can be overcome by deleting the parentheses " [" and "] ".

Claim Rejections - 35 USC § 103

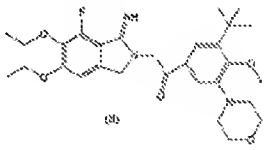
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

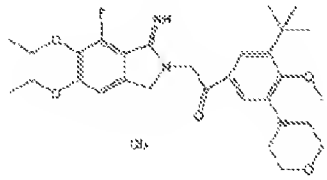
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 are rejected under 35 U.S.C. 103 (a) as unpatentable over U.S. Patent No. 7,244,730 ("the `730 patent") by Suzuki et al. in view of FDA drug Application No. *NDA #019437* (AMINOSYN II).

Applicant's instantly elected invention of claims 1-5 are related to a composition comprising the elected species of the compound  and at least one type of electrolyte selected from the group consisting of halide salts of alkaline metal, or alkaline earth metal,.. etc.

Determination of the scope and content of the prior art (MPEP §2141.01)

The `730 patent teaches a composition comprising a compound



in claim 13. The compound is formulated as a pharmaceutical composition as oral or injectable form according to the prior art teachings at lines 42 column 123 through lines 18 column 125, may further comprisng pH adjustors, and/or stabilizing agents.

The FDA application of drug application AMINOSYN, *NDA #019437* taught injectable drug formulation containing electrolytes such as sodium chloride, magnesium chloride or potassium chloride.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the cited `730 prior art composition and the instantly claimed composition is that the prior art does not specifically teach electrolyte such as sodium chloride, potassium chloride in the formulation, but teach a pharmaceutical formulation further comprising pH adjustors, and/or stabilizing agents.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The instantly claimed compositions would have been obvious over the combined prior art teachings of the compositions. It is because the `730 patent teaches a pharmaceutical composition comprising the instantly elected species of the compound, and additional ingredient such as pH adjustors, and/or stabilizing agents. The non-specifically disclosed additional electrolytes such as sodium chloride or potassium chloride are taught in the other *NDA #019437* pharmaceutical compositions, which

comprises electrolytes, such as sodium, potassium chloride in injectable drug formulations. One ordinary skilled in the art would have been motivated to prepare the instant formulation based on the prior art teachings. Finding the ratio between the active compound and electrolytes in a formulation is at the grasp of a pharmaceutical formulation scientist. It is a routine experimental practice. The motivation to make the claimed compositions derives from the expectation that the electrolyte ingredients used for one drug formulation will apply to another similar formulation. Therefore, the instantly claimed compositions would have been suggested to one skilled in the art.

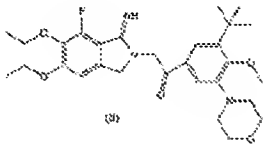
Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

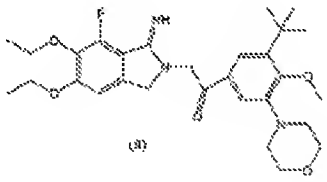
A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 14 of U.S. Patent No. 7,244,730 ("the `730 patent"). Although the conflicting claims are not identical, they are not patentably distinct from each other because the description as follows:

Applicant's instantly elected invention of claims 1-5 are related to a composition comprising the elected species of the compound  and at least one type of electrolyte selected from the group consisting of halide salts of alkaline metal, or alkaline earth metal,.. etc.

Determination of the scope and content of the prior art (MPEP §2141.01)

Claims 13 and 14 of the `730 patent teaches a composition comprising the compound  in claim 13. The compound is formulated as a pharmaceutical composition as oral or injectable form according to the prior art teachings at lines 42 column 123 through lines 18 column 125, such as using pH adjustors, and stabilizing agent.

The FDA application of drug application AMINOSYN, *NDA #019437* taught injectable drug formulation containing electrolytes such as sodium chloride, magnesium chloride or potassium chloride.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the cited `730 prior art composition and the instantly claimed composition is that the prior art does not specifically teach electrolyte such as sodium chloride, potassium chloride in the formulation, but teach a pharmaceutical formulation further comprising pH adjustors, and/or stabilizing agents.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The instantly claimed compositions would have been obvious over the combined prior art teachings of the compositions. It is because the `730 patent teaches a pharmaceutical composition comprising the instantly elected species of the compound, and additional ingredient such as pH adjustors, and stabilizing agents. The non-specifically disclosed additional electrolytes such as sodium chloride or potassium chloride are taught in the other *NDA #019437* drug compositions, which have sodium, potassium chloride electrolytes in the injectable formulations. One ordinary skilled in the art would have been motivated to prepare the instant formulation based on the prior art teachings. Finding the ratio between the active compound and electrolytes are at the grasp of a pharmaceutical formulation scientist. It is a routine pharmaceutical practice. The motivation to make the claimed compositions derives from the expectation that the electrolyte ingredients used for one drug formulation will apply to another similar formulation. Therefore, the instantly claimed compositions would have been suggested to one skilled in the art.

Conclusion

- Claims 1-5 are objected to.
- Claims 1-5 are rejected.
- Specification is objected to.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./
Patent Examiner
Art Unit 1626